REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Claims 18, 21-23 and 27-33 are under consideration, with claims 18, 21 and 28-30 being in independent format

Claims 23 and 27-33 have been amended to correct minor typographical errors as requested by the Examiner. It is submitted that support for these amendments may be found throughout the specification as originally found and that none of the amendments constitute new matter. It is further submitted that, as these amendments are non-substantive, they do not give rise to prosecution history estoppel.

Claim Rejection under 35 USC §101

The pending claims stand rejected under 35 USC §101 as lacking either a specific and substantially asserted utility or a well-established utility. This rejection is respectfully traversed.

The pending claims are drawn, in part, to a polypeptide comprising the amino acid sequence of SEQ ID NO: 172 which is encoded by the DNA sequence of SEQ ID NO: 73, and is referred to as AP4. As clearly stated in Table 1 (page 71) of the specification as originally filed, SEQ ID NO: 73 encodes a pyruvate oxidase. This utility is supported by the Declaration of Dr. James Dekker submitted herewith, which describes studies demonstrating that SEQ ID NO: 73 does indeed encode a pyruvate oxidase polypeptide.

It is thus submitted that the claimed invention possesses a utility that is both substantial and credible, and that the rejection of the claims under 35 USC §101 may thus be properly withdrawn.

Claim Rejection under 35 USC §112, first paragraph – written description

Claims 22 and 27-33 stand rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement. This rejection is respectfully traversed.

With regards to the rejection of claim 22, applicants are unaware of any requirement that a claim to a fusion protein including a specific amino acid sequence recite the function of the amino acid sequence. Rather the question is whether or not one of skill in the art would agree that the inventors were in possession of the claimed invention at the time the application was filed. Indeed, the applicants note that the Patent Office regularly issues patents including claims to fusion proteins/polypeptides that do not recite the function of the fusion protein/polypeptide (see, for

example US Patent 7,060,676, issued June 13, 2006, and US Patents 7,053,045 and 7,052,703, both issued on May 30, 2006).

It is urged that one of skill in the art, on being provided with the instant specification, would indeed believe that the inventors were in possession of the fusion proteins recited in claim 22 at the filing date of the application and that this rejection of claim 22 should therefore be withdrawn.

With regards to the rejection of claims 28-33, the Examiner asserts that these claims are new matter on the basis that "neither the specification nor the claims as originally filed state that the polypeptide set forth in SEQ ID NO: 172 possesses pyruvate oxidase". The applicants strenuously disagree with the Examiner's position. Table 1 (page 71) of the specification clearly states that the polynucleotide sequence of SEQ ID NO: 73 is a "Homologue of poxB, encoding a pyruvate oxidase (EC 1.2.3.3), which decarboxylates pyruvate". It is urged that one of skill in the art would reasonably understand this statement to mean that SEQ ID NO: 73 encodes a polypeptide having pyruvate oxidase activity, and that therefore claims 28-33 are drawn to subject matter which was indeed described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. Applicants submit that this rejection of claims 28-33 may thus be properly withdrawn.

Claim Rejection under 35 USC §112, first paragraph - enablement

All the pending claims stand rejected under 35 USC §112, first paragraph, as lacking an enabling disclosure. Specifically, the Examiner states that "because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, one of skill in the art would not know how to use the claimed invention".

As discussed above, the specification as originally filed clearly asserts a specific and substantial utility for the claimed invention, and this utility is clearly supported by the Declaration of Dr. James Dekker submitted herewith. It is therefore submitted that one of skill in the art, on being provided with the instant specification, would indeed be able to practice the claimed invention without undue experimentation and that this rejection of claims 18, 21-23 and 27-33 may be properly withdrawn.

The Examiner has additionally rejected claims 28, 29, 31 and 32 under 35 USC §112, first paragraph as lacking an enabling disclosure, on the basis that the specification does not enable polypeptides having at least 75% or 90% identity to SEQ ID NO: 172 and retaining pyruvate oxidase activity. This rejection is respectfully traversed.

The Examiner asserts that "lack of teaching the structure/function relationship and lack of instruction as to which amino acids can be changed without loosing the required enzymatic activity, imposes on the skilled artisan experimentation that has low probability of success". Applicants respectfully disagree. As discussed in the Declaration of Dr. James Dekker submitted herewith, the amino acids important for enzyme activity of pyruvate oxidases were known to those of skill in the art prior to filing of the subject patent application (see, for example Muller et al., *J. Mol. Biol. 237*:315-335 (1994); abstract submitted herewith for the Examiner's convenience). Thus one of skill in the art, on being provided with the instant specification, would be able to identify areas within the sequence of SEQ ID NO: 172 that are important for activity of the molecule, and would be able to prepare and use polypeptides having 75% or 90% identity to SEQ ID NO: 172 that retain the amino acids important for activity and thus have pyruvate oxidase activity, without undue experimentation.

It is therefore urged that claims 28, 29, 31 and 32 do indeed satisfy the enablement requirement and that this rejection of claims 28, 29, 31 and 32 under 35 USC §112, first paragraph, may be properly withdrawn.

Concluding Remarks

A request for a two month extension of time, extending the deadline for response to June 26, 2006, is submitted herewith.

Early consideration and allowance of the pending claims is respectfully requested. Should the Examiner have any concerns regarding the subject patent application, he/she is respectfully requested to telephone the undersigned at: 206.382.1191.

Respectfully submitted,

Janet Sleath
Registration No. 37,007

Date: June 26, 2006

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1: J Mol Biol. 1994 Apr 1;237(3):315-35. Related Articles, Links
ELSEVIER FULL-TEXT ARTICLE

The refined structures of a stabilized mutant and of wild-type pyruvate oxidase from Lactobacillus plantarum.

Muller YA, Schumacher G, Rudolph R, Schulz GE.

Institut fur Organische Chemie und Biochemie, Albert-Ludwigs-Universitat, Freiburg, Germany.

The crystal structure of pyruvate oxidase (EC 1.2.3.3) from Lactobacillus plantarum stabilized by three point mutations has been refined at 2.1 A resolution using the simulated annealing method. Based on 87,775 independent reflections in the resolution range 10 to 2.1 A, a final R-factor of 16.2% was obtained at good model geometry. The wild-type enzyme crystallizes isomorphously with the stabilized enzyme and has been analyzed at 2.5 A resolution. Pyruvate oxidase is a homotetramer with point group symmetry D2. One 2-fold axis is crystallographic, the others are local. The crystallographic asymmetric unit contains two subunits, and the model consists of the two polypeptide chains (residues 9 through 593), two FAD, two ThDP*Mg2+ and 739 water molecules. Each subunit has three domains; the CORE domain, the FAD domain and the ThDP domain. The FAD-binding chain fold is different from those of other known flavoproteins, whereas the ThDP-binding chain fold resembles the corresponding folds of the two other ThDP enzymes whose structure is known, transketolase and pyruvate decarboxylase. The peptide environment most likely forces the pyrimidine ring of ThDP into an unusual tautomeric form, which is required for catalysis. The structural differences between the wild-type and the stabilized enzyme are small. All three point mutations are at or near to the subunit interfaces, indicating that they stabilize the quarternary structure as had been deduced from reconstitution experiments.

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